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1626/44

Attorney Docket No. LeA 33535

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bischoff, et al.

Group Art Unit: 1626

Serial No: 09/980,242

Examiner: R. Anderson

Filed: 11/29/2001

For: Substituted Phenylcyclohexanecarboxamides and their Use as Adenosine-Uptake Inhibitors

CERTIFICATION OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence and any papers referred to as attached are being deposited, on the date shown below, with the United States Postal Service, with sufficient postage, as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 29 Jun '03


William F. Gray

Response to Restriction Requirement

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Assistant Commissioner for Patents

JUN 05 2003

Washington, DC 20231

TECH CENTER 1600/2900

Sir:

This is in response to the official action dated 03/31/2003.

In response to the restriction requirement, the applicants hereby elect to proceed with prosecution of restriction group IV, relating to claims 1-6, 8, 16, and 21-62 drawn to products of formula I, as defined in the office action, plus process for their preparation, and methods for their use.

In the restriction requirement, the examiner appears to have overlooked the fact that when the group R² is piperazinyl, the group R⁷ is necessarily present. Accordingly, the applicants

assume that the examiner's definition of restriction group IV also includes R⁷ as defined in claim 1.

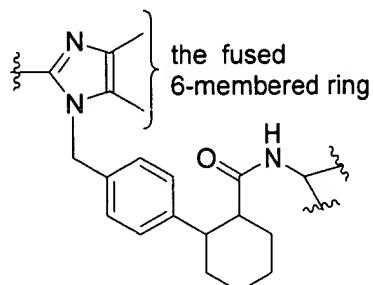
The examiner states that "the claims lack unity of invention since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The technical feature of claims 14 and 15 differ from each other and from the compounds of claims 1-6, 8-13, 16, and 21-62. Also, the compounds in claims 1-6, 8-13, 16, and 21-62 all contain a cyclohexyl benzimidazole, which does not define a contribution over the prior art (as can be seen by the compounds on page 4 of EP 0725064A1). The substituents on the cyclohexyl benzimidazole vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter."

The examiner is deemed to have misinterpreted the rules concerning unity of invention in the context of a Markush claim. Under PCT rule 13, where there is more than one invention in a PCT application, these are considered linked so as to form a single general inventive concept only when there is a technical relationship involving one or more of the same or corresponding "special technical features". The expression "special technical features" means those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Annex B of the PCT Administrative Instructions explains the method for determining unity of invention with respect to Markush practice as follows. The requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2 are considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature if the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present official action, the examiner's statement that the claims lack unity of invention arguably misapprehends the rules regarding Markush claims, set forth above. In the present case, (A) all the claimed compounds are asserted to have a common property or activity, namely, inhibiting adenosine uptake, and (B) a common structure is present, namely,



This is much more than the cyclohexyl benzimidazole asserted by the examiner, and arguably qualifies as a significant structural element shared by all of the alternative compounds. Accordingly, it is deemed that unity of invention is present for the compounds defined by claim 1. As these compounds are employed in the claimed pharmaceutical compositions, are made by the claimed method of making, and are employed in the claimed methods of use, it is further deemed that unity of invention exists with regard to those different categories of claims.

Applicants do not dispute the examiner's conclusion that claims 14 and 15 lack unity of invention.

Respectfully submitted,

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